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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,501	12/21/2001	Heinz Anderle	20695C-003000US (P-255.00	4623

20350 7590 10/03/2003

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EXAMINER	
LANKFORD JR, LEON B	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,501	ANDERLE ET AL.	
	Examiner	Art Unit	
	L Blaine Lankford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-42 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-42 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 & 25-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant claims the deactivation of "pathogens" however the specifications limited showing of the deactivation of enveloped viruses is not adequate written description for such a broad recitation. Applicant does not describe how to use the method in order to deactivate pathogens other than enveloped viruses. Pathogens encompasses many agents beyond enveloped viruses and it would require undue experimentation to determine which pathogens this method may or may not be effective in deactivating.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rendered indefinite because the claims call for the use of a detergent and a carboxylic acid ester but many of such esters are categorized as detergents (including some claimed by applicant such as Tween 80). Therefore it is unclear whether applicant intends for the invention to comprise two distinct antipathogen agents or if one will suffice. Please note that the language of a claim must make it clear what subject matter the claim encompasses to adequately delineate its "metes and bounds". See, e.g., the following decisions: In re Hammack, 427 F 2d. 1378, 1382, 166 USPQ 204, 208 (CCPA 1970); In re Venezia 530 F 2d. 956, 958, 189 USPQ 149, 151 (CCPA 1976); In re Goffe, 526 F 2d. 1393, 1397, 188 USPQ 131, 135 (CCPA 1975); In re Watson, 517 F 2d. 465, 477, 186 USPQ 11, 20 (CCPA 1975); In re Knowlton 481 F 2d. 1357, 1366, 178 USPQ 486, 492 (CCPA 1973).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Werner (3655871) or Horowitz et al(4841023) or Prince (4481189) or Shanbrom(4314997).

Applicant claims a method of deactivating a pathogen by incubating it with a detergent and a carboxylic acid ester.

Werner, Horowitz et al, Prince and Shanbrom all teach the inactivation of viruses using carboxylic acid ester ranging from acetic acid (Werner) to Sorbitol esters (Prince). Many of these carboxylic acid esters are also classified as detergents.

The references do not appear to teach using applicant's specific combination or exact ratio of components nor do the references teach all of applicant's embodied esters or detergents. What the references provide is that it is old and well known that

carboxylic acid esters of varying size and complexity are effective inactivating agents for enveloped viruses. The esters are taught to disrupt the lipid envelopes and thus inactivate the viruses. As the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed method are result effective variables, they would be routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by those references. Also as the prior art teaches that a wide variety of carboxylic acid esters are useful in such a procedure and that the prior art also teaches the mechanism of action, it would have been obvious to deactivate viral pathogens using the carboxylic acids claimed because the prior art clearly provides a reasonable expectation of success that a carboxylic acid ester will inactivate a lipid enveloped virus.

Given that the prior art clearly teaches that carboxylic acid esters are old and well known to inactivate viruses and that detergents (some of which are carboxylic acid esters) are notoriously old and well known in the art for the ability to deactivate pathogens, it would have been obvious at the time the invention was made to combine such an ester and a known detergent because it is a well established proposition of patent law that no patentable invention resides in combining old ingredients of known characteristics where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman,* 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett et al,* 1266 USPQ 186.

Accordingly, the claimed invention was prima facie obvious to one of ordinary

skill in the art at the time the invention was made especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to L Blaine Lankford whose telephone number is 308-2455. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0196.

L Blaine Lankford
Primary Examiner
Art Unit 1651